PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In re Application of:	**Joseph C. Eder and Alejandro Berenstein**
Application No.:	**10/063315**
Filed:	**April 10, 2002**
For:	**Hybrid Stent**
Examiner:	**Ryan J. Severson**
Group Art Unit:	**3731**

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Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Docket No.: S63.2B-10039-US01

APPEAL BRIEF

This is an Appeal Brief for the above-identified application, in which pending claims 38 – 41 and 43 – 55 were rejected in a Final Office Action dated April 11, 2008.

A Notice of Appeal was filed in this case on July 10, 2008. The fee required for submitting this Appeal Brief under 37 C.F.R. § 41.20(b) is addressed in a concurrently filed transmittal letter. The Commissioner is authorized to charge Deposit Account No. 22-0350 for any other fees that may be due with this Appeal.

(i) Real Party in Interest

The Application is assigned to Boston Scientific Scimed, Inc., formerly known as Scimed Life Systems, Inc., One SciMed Place, Maple Grove, Minnesota 55311-1566, a Minnesota corporation and a subsidiary of Boston Scientific Corporation, One Boston Scientific Place, Natick, Massachusetts 01760-1537, a Delaware Corporation.

(ii) Related Appeals and Interferences

There are no related appeals or interferences which will directly affect or be affected by or have a bearing on the Board's decision in the pending appeal.

(iii) Status of the Claims

Claims 38 – 41 and 43 – 55 are pending in this application, all of which were finally rejected and are the subject of this Appeal.

Claims 1 – 37 and 42 were canceled during prosecution.

(iv) Status of Amendments

Applicants filed a Response After Final on June 6, 2008. Although Applicants did not submit any amendments, the Advisory Action stated that the "proposed amendment will not be entered."

(v) Summary of Claimed Subject Matter

A summary of the representative independent claim, as required by 37 C.F.R. § 41.37(c)(1)(v), and a non-limiting listing of locations where support may be found [bracket citations] is provided as follows:

Claim 38 is directed to a stent having a longitudinal axis comprising a plurality of segments, including at least one coil segment connected to at least one serpentine segment. [FIGs. 1A, 1B, 2; ¶¶ [0010], [0041]]. The at least one serpentine segment forms an annular ring about the longitudinal axis of the stent. [FIGs. 1A, 1B, 2]. The at least one coil segment has curved portions that extend at least 90 degrees about the longitudinal axis. [FIGs. 1A, 1B, 2]. Immediately adjacent curved portions are longitudinally offset and have a substantially constant longitudinal distance between each other. [FIGs. 1A, 1B, 2]. Each of the at least one coil segments extends along a greater longitudinal distance than each of the at least one serpentine segments. [FIGs. 1A, 1B, 2]. Either the coil segment is balloon expandable and not self-expanding and the serpentine segment is self-expanding and not balloon expandable, or the coil segment is self-expanding and not balloon expandable and the serpentine segment is balloon expandable and not self-expanding. [¶¶ [0010], [0012], [0049]].

Claim 46 is directed to a stent comprising a coil segment and a tubular, serpentine segment. [FIGs. 1A, 1B, 2; ¶¶[0010-0011]]. The coil segment is longer than the tubular serpentine segment in a longitudinal direction. [FIGs. 1A, 1B, 2]. The coil segment has curved portions that extend at least 90 degrees about the longitudinal axis. [FIGs. 1A, 1B, 2]. Immediately adjacent curved portions are longitudinally offset and have a substantially constant distance between each other. [FIGs. 1A, 1B, 2]. Either the coil segment is balloon expandable and not self-expanding and the serpentine segment is self-expanding and not balloon expandable,

or the coil segment is self-expanding and not balloon expandable and the serpentine segment is balloon expandable and not self-expanding. [¶¶ [0010], [0012], [0049]].

(vi) Grounds of Rejection to be Reviewed on Appeal

I. Whether the Examiner erred in rejecting claims 38 – 41, 44, 46 – 49, and 51 – 55 under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,817,126 to Imran (hereafter "Imran") in view of U.S. Patent No. 6,336,937 to Vonesh et al. (hereafter "Vonesh").

II. Whether the Examiner erred in rejecting claims 43, 45, and 50 under 35 U.S.C. § 103(a) as being unpatentable over Imran in view of Vonesh and further in view of U.S. Patent No. 5,593,442 to Klein (hereafter "Klein").

(vii) Arguments

I. Rejection Of Claims 38 – 41, 44, 46 – 49, And 51 – 55 Under 35 U.S.C. § 103(a) As Being Unpatentable Over Imran In View Of Vonesh.

Claim 38 and Those Claims Dependent Therefrom

A Braided Segment Is Not A Coil Segment

The purported combination of Imran and Vonesh fails to teach or suggest all the limitations of instant claim 38. Claim 38 recites, "A stent having a longitudinal axis comprising a plurality of segments, including at least one coil segment connected to at least one serpentine segment..." The Examiner asserted that FIG. 1 of Imran "discloses a stent having a coil segment (60) and serpentine segments (20 and 40)." Applicants respectfully assert that this is incorrect.

Segment 60 of Imran is a ***braided*** segment, as specified in the Imran specification ("Strands 62, 64 making up the ***braided*** intermediate segment 60..." (col. 4, lines 24 – 25)(Emphasis added)). Applicants' specification, however, specifically ***excludes*** braided segments from being considered coil segments. At paragraph [0040], Applicants state, "Also, the ***term 'coil segment' excludes segments*** which are in the form of a multiplicity of wires or strands ***which are woven or braided*** such as that disclosed in U.S. Pat. No. 5,061,275." (Emphasis added).

The Office is entitled to give the claims the broadest reasonable interpretation. However, "The Patent and Trademark Office ("PTO") determines the scope of claims... upon giving claims their broadest reasonable construction ***'in light of the specification as it would be interpreted by one of ordinary skill in the art.***'" MPEP § 2111, citing In re Am. Acad. of Sci. Tech. Ctr., 367 F.3d 1359, 1364[, 70 USPQ2d 1827] (Fed. Cir. 2004)(Emphasis added).

It would be clear to a person of ordinary skill in the art that segment 60 of Imran is

a braided segment. And, it would also be clear to a person of ordinary skill in the art, ***in light of Applicants' specification***, that a braided segment is considered to be a type of ***non-coil*** segment.

In the Advisory Action, the Examiner agreed that claims are read in light of the specification, but then asserted that

> limitations from the specification are not read into the claims. The claims only require a segment that is coiled. The braided segment is made up of strands (62 and 64) that are coiled about the longitudinal axis of the stent. The claims do no prevent such an interpretation given their broadest reasonable interpretation.

Applicants assert that this statement is in error. Applicants assert that the Examiner has failed to give the claims their broadest reasonable interpretation, ***in light of the specification***, as it would be interpreted by a person of ordinary skill in the art. Rather, it appears to Applicants that the Examiner has ***completely disregarded the specification*** when interpreting the claims.

The case law is clear on the role that the specification plays in construing the claim terms. The court in Phillips v. AWH Corporation, 75 USPQ2d 1321, 1327 (Fed. Cir. 2005) stated that "[t]his court and its predecessors have long emphasized the importance of the specification in claim construction." "'The words of patent claims have the meaning and scope with which they are used in the specification and the prosecution history.'" Id. at 1328, quoting Moba, B.V. v. Diamond Automation, Inc., 325 F.3d 1306, 1315 [66 USPQ2d 1429] (Fed. Cir. 2003). "'The claims are directed to the invention that is described in the specification; they do not have meaning removed from the context from which they arose.'" Id., quoting Netword, LLC v. Centraal Corp., 242 F.3d 1347, 1352 [58 USPQ2d 1076] (Fed. Cir. 2001). "'A fundamental rule of claim construction is that terms in a patent document are construed with the meaning with which they are presented in the patent document. Thus claims must be construed so as to be consistent with the specification, of which they are a part.'" Id., quoting Merck & Co. v. Teva

Pharms. USA, Inc., 347 F.3d 1367, 1371 [68 USPQ2d 1857] (Fed. Cir. 2003).

The Phillips court continued, stating that

> Consistent with that general principle, our cases recognize that **the specification may reveal a special definition given to a claim term by the patentee that differs from the meaning it would otherwise possess. In such cases, the inventor's lexicography governs.** See CCS Fitness, Inc. v. Brunswick Corp., 288 F.3d 1359, 1366 [62 USPQ2d 1658] (Fed. Cir. 2002). In other cases, the specification may reveal an intentional disclaimer, or disavowal, of claim scope by the inventor. In that instance as well, the inventor has dictated the correct claim scope, and the inventor's intention, as expressed in the specification, is regarded as dispositive. See SciMed Life Sys., Inc. v. Advanced Cardiovascular Sys., Inc., 242 F.3d 1337, 1343-44 [58 USPQ2d 1059] (Fed. Cir. 2001).

Id. at 1329. (Emphasis added)

In the instant case, Applicants have provided a definition of "coil segment" in the specification: "the term 'coil segment' excludes segments which are in the form of a multiplicity of wires or strands which are woven or braided such as that disclosed in U.S. Pat. No. 5,061,275." (¶ [0040]). As such, this definition controls the interpretation of the claim term "coil segment."

The Examiner takes the untenable position in the Advisory Action of acknowledging that, on the one hand, claims are interpreted in light of the specification, yet on the other hand completely ignoring the explicit definition of a claim term set forth by Applicants in the specification. Applicants note that MPEP § 2145, VI. "Arguing Limitations Which Are Not Claimed" does not provide support for the Examiner's position. This section, and its supporting case law, is not applicable in the instant case for the simple reason that Applicants specification ***did*** provide explicit evidence indicating that this definition must be read into the claims to give the claim term "coil segment" its desired meaning. Applicants assert that their explicit definition is

not a mere "limitation" as is contended by the Examiner, and as such, the definition must control the scope of the claim term "coil segment."

Thus, to the extent, for the sake of argument only, that the first end segment 20 and second end segment 40 of Imran are ***serpentine*** segments, as was asserted by the Office, Imran discloses a stent having three non-coil segments, and no coil segments. Therefore, Imran does not teach or suggest "A stent having a longitudinal axis comprising a plurality of segments, including at least one coil segment connected to at least one serpentine segment...," as recited in claim 38.

Regarding the secondary reference Vonesh, the Office alleges that Vonesh teaches that a stent may have self-expanding segments adjacent to balloon expandable segments. However, any alleged disclosure in the Vonesh reference of self-expanding segments combined with balloon expandable segments in a stent does nothing to address the failure of Imran to teach a stent having at least one coil segment connected to at least one serpentine segment, as in claim 38. Thus, claim 38 is non-obvious over the combination of Imran and Vonesh.

Claims 39 – 41, 44, and 54 – 55 depend from claim 38, making them non-obvious as well over the combination of Imran and Vonesh. Applicants request that the rejection be withdrawn and that claims 38 – 41, 44, and 54 – 55 be allowed.

Claim 46 and Those Claims Dependent Therefrom

A Braided Segment Is Not A Coil Segment

The purported combination of Imran and Vonesh fails to teach or suggest all the limitations of instant claim 46. Claim 46 is directed toward a stent comprising a coil segment and a tubular, serpentine segment. For at least the reasons presented above with respect to claim 38,

the braided segment of Imran is ***not*** a coil segment, as the claim term is explicitly defined in the instant application. As such, Imran does not disclose a stent with a coil segment and a tubular, serpentine segment.

The addition of Vonesh does nothing to remedy the deficiencies of Imran. Thus, the purported combination of Imran and Vonesh fails to teach or suggest the stent of claim 46. As such, claim 46 is non-obvious.

Claims 47 – 49 and 51 – 53 depend from claim 46, making them non-obvious as well over the combination of Imran and Vonesh. Applicants request that the rejection be withdrawn and that claims 46 – 49 and 51 – 53 be allowed.

II. Rejection Of Claims 43, 45, And 50 Under 35 U.S.C. § 103(a) As Being Unpatentable Over Imran In View Of Vonesh And Further In View Of Klein.

Regarding Claims 43 and 45

As argued above, the purported combination of Imran and Vonesh fails to teach or suggest all the limitations of claim 38, from which claims 43 and 45 depend. The addition of any alleged teaching in Klein of using spring steel in stents does nothing to address the failure of the Imran/Vonesh combination to teach or suggest all the elements of claim 38. To that end, claims 43 and 45 are non-obvious. Applicants request that the rejection be withdrawn and that claims 43 and 45 be allowed.

Regarding Claim 50

As argued above, the purported combination of Imran and Vonesh fails to teach or suggest all the limitations of claim 46, from which claim 50 depends. The addition of any

alleged teaching in Klein of using spring steel in stents does nothing to address the failure of the Imran/Vonesh combination to teach or suggest all the elements of claim 46. To that end, claim 50 is non-obvious. Applicants request that the rejection be withdrawn and that claim 50 be allowed.

Conclusion

For at least the reasons discussed above, the subject matter in claims 38 – 41 and 43 – 55 is patentably distinct over the cited art. Consequently, reversal of the rejections is respectfully requested.

Respectfully submitted,

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(viii) Claims Appendix

38. A stent having a longitudinal axis comprising a plurality of segments, including at least one coil segment connected to at least one serpentine segment, the at least one serpentine segment forming an annular ring about the longitudinal axis of the stent, the at least one coil segment having curved portions that extend at least 90 degrees about the longitudinal axis, immediately adjacent curved portions being longitudinally offset and having a substantially constant longitudinal distance between each other, each of the at least one coil segments extending along a greater longitudinal distance than each of the at least one serpentine segments, wherein either the coil segment is balloon expandable and not self-expanding and the serpentine segment is self-expanding and not balloon expandable, or the coil segment is self-expanding and not balloon expandable and the serpentine segment is balloon expandable and not self-expanding.

39. The stent of claim 38 having a first end segment and a second end segment, wherein each of the first and second end segments is an expandable serpentine segment.

40. The stent of claim 39 comprising only one segment which is in the form of a coil and which connects the first and second end segments.

41. The stent of claim 40 wherein the first and second end segments are self-expandable.

43. The stent of claim 41 wherein the first and second segments are made of spring steel.

44. The stent of claim 40 wherein the first and second end segments are balloon expandable.

45. The stent of claim 38 wherein the segment which is in the form of a coil is made of spring steel.

46. A stent comprising a coil segment and a tubular, serpentine segment, the coil segment being longer than the tubular serpentine segment in a longitudinal direction, the coil segment having curved portions that extend at least 90 degrees about the longitudinal axis, immediately

adjacent curved portions being longitudinally offset and having a substantially constant distance between each other, wherein either the coil segment is balloon expandable and not self-expanding and the serpentine segment is self-expanding and not balloon expandable, or the coil segment is self-expanding and not balloon expandable and the serpentine segment is balloon expandable and not self-expanding.

47. The stent of claim 46 wherein the tubular, serpentine segment is balloon expandable.

48. The stent of claim 46 wherein the tubular, serpentine segment is self-expandable.

49. The stent of claim 46 having a first end and a second end, the first end being a tubular, serpentine segment and the second end being a tubular, serpentine segment.

50. The stent of claim 46 where the coil segment is made of spring steel.

51. The stent of claim 46 wherein the coil segment has an outer diameter of no more than 6 mm when deployed.

52. The stent of claim 51 having an outer diameter of no more than 6 mm when deployed.

53. The stent of claim 51 having a length of no more than 20 mm.

54. The stent of claim 38, wherein at least one coil segment is expandable by self-expansion and at least one serpentine segment is expandable by balloon expansion.

55. The stent of claim 38, wherein at least one coil segment is expandable by balloon-expansion and at least one serpentine segment is expandable by self-expansion.

(ix) Evidence Appendix

None.

(x) Related Proceedings Appendix

None.